IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
Southern Division

IMPACT APPLICATIONS, INC.,	*	
Plaintiff,	*	
v.		**Case No.: GJH-19-3108**
	*	
CONCUSSION MANAGEMENT, LLC,	*	
Defendant.	*	

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MEMORANDUM OPINION

Plaintiff ImPACT Applications, Inc. ("ImPACT Applications" or "Plaintiff"), brought this civil action against Defendant Concussion Management, LLC f/k/a XLNTbrain, LLC ("XLNTbrain" or "Defendant"), alleging false advertising in violation of the Lanham Act, 15 U.S.C. § 1125(a) (Count I), and common law unfair competition (Count II). ECF No. 19. Pending before the Court are Defendant's Motion for Judgment on the Pleadings as to Plaintiff's Amended Complaint, ECF No. 23, and Plaintiff's Motion for Leave to File Surreply, ECF No. 27.[1] No hearing is necessary. *See* Loc. R. 105.6 (D. Md. 2018). For the following reasons, Defendant's Motion for Judgment on the Pleadings is granted and Plaintiff's Motion for Leave to File Surreply is denied.

[1] Also pending before the Court is Plaintiff's Consent Motion to Extend Deadline to Respond to Second Motion for Judgment on the Pleadings, ECF No. 24, which the Court grants.

I. BACKGROUND[2]

A. The Parties

ImPACT Applications was founded by a group of medical and research professionals in 2002. ECF No. 19 ¶ 6. Its primary business operations include training and software for neurocognitive testing, assessment, and evaluation for use in ImPACT Applications' proprietary computerized neurocognitive evaluation system. *Id.* ¶ 7. ImPACT Applications is the maker of ImPACT® (Immediate Post-concussion Assessment and Cognitive Testing), which provides a neurocognitive test battery that offers healthcare professionals objective measures of neurocognitive functioning. *Id.* ¶ 8. Healthcare professionals use ImPACT®, and the data it provides, as an aid in the assessment and management of concussions in individuals between the ages of 12 and 59. *Id.* ImPACT Applications is also the maker of ImPACT Pediatric®, which is similar to ImPACT®, but used for individuals between the ages of 5 and 11. *Id.* ¶ 10. ImPACT® and ImPACT Pediatric® are the result of years of research and are the only software-based neurocognitive tests that have been cleared and designated by the Food and Drug Administration ("FDA") as Class II medical devices for use as an aid in the assessment and management of concussions. *Id.* ¶¶ 9, 12, 15. The ImPACT® test is used globally by high schools, colleges, universities, clinical centers, consultants, professional teams, and military units. *Id.* ¶ 19.

XLNTbrain, LLC was organized in Maryland in 2012 with a stated purpose of assessing neurological activity in athletes in order to enhance their performance.[3] *Id.* ¶¶ 28–29. XLNTbrain markets and sells its products to schools, medical professionals, and sports teams and is a direct competitor of ImPACT Applications. *Id.* ¶¶ 30–31.

[2] Unless otherwise stated, the background facts are taken from Plaintiff's Amended Complaint, ECF No. 19, and are presumed to be true.
[3] XLNTbrain, LLC changed its corporate name to Concussion Management, LLC on January 6, 2016. ECF No. 19 ¶ 28.

B. Concussions And Traumatic Brain Injuries

Traumatic brain injuries, and more specifically concussions, are of great public concern in the United States. *Id.* ¶ 17. According to an article published on the National Center for Biotechnology Information ("NCBI") website, each year an estimated 38 million children and adolescents participate in organized sports in the United States, with an additional 170 million adults participating in similar physical activities. *Id.* ¶ 20 (citing Daniel H. Daneshvar et al., *The Epidemiology of Sport-Related Concussion*, National Center for Biotechnology Information – PubMed Central (Jan. 1, 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2987636/). Many of these activities are associated with an increased risk of traumatic brain injury, with 1.6 to 3.8 million concussions occurring in sports and recreational activities annually. *Id.* Additionally, each year traumatic brain injuries account for more than 2 million emergency room visits in the United States and contribute to the deaths of more than 50,000 Americans. *Id.* ¶ 21.

The FDA issued a safety communication on April 10, 2019, targeted at people who may be tested for a head injury, parents and caregivers of people who may be tested, coaches and athletic administrators, sports medicine specialists and athletic trainers, and health care providers who assess or diagnose head injuries. *The FDA Recommends Only Using Cleared or Approved Medical Devices to Help Assess or Diagnose a Head Injury, Including Concussion: FDA Safety Communication*, U.S. Food & Drug Administration (Apr. 10, 2019), https://www.fda.gov/medical-devices/safety-communications/fda-recommends-only-using-cleared-or-approved-medical-devices-help-assess-or-diagnose-head-injury.[4] This safety

[4] The Amended Complaint references such a statement made by the FDA but appears to provide the wrong date. ECF No. 19 ¶ 24 & n.2. Regardless, the Court can take judicial notice of the FDA's safety communication and news release. *See United States v. Garcia*, 855 F.3d 615, 621 (4th Cir. 2017) (noting courts "routinely take judicial notice of information contained on state and federal government websites"); *Horne v. Novartis Pharm. Corp.*, 541 F. Supp. 2d 768, 777 (W.D.N.C. 2008) ("[T]he Court may take judicial notice of and consider the public records of the FDA, such as [a] Public Health Advisory[.]").

communication recommends that the target audience use only cleared or approved medical devices to help assess or diagnose a head injury, including a concussion. *Id.* Additionally, a news release relating to the safety communication clarifies that "[p]roducts being marketed for the assessment, diagnosis, or management of a head injury, including concussion, that have not been approved or cleared by the FDA are in violation of the law." *FDA warns public not to sue unapproved or uncleared medical devises to help assess or diagnose a concussion*, U.S. Food & Drug Administration (Apr. 10, 2019), https://www.fda.gov/news-events/press-announcements/fda-warns-public-not-use-unapproved-or-uncleared-medical-devices-help-assess-or-diagnose-concussion.

ImPACT Applications' products are included in the FDA's list of approved medical devises for assessing head injury. *Medical Devices for Assessing Head Injury*, U.S. Food & Drug Administration (Apr. 9, 2019), https://www.fda.gov/medical-devices/neurological-devices/medical-devices-assessing-head-injury. XLNTbrain's products are not. *Id.*

C. XLNTbrain's Alleged False And Misleading Statements

XLNTbrain makes numerous statements on its website and social media accounts that ImPACT Applications alleges are false and misleading. These allegedly false statements include claims that "the XLNT brain test is superior to and more effective than other concussion assessment tools, including neurocognitive tests" as well as claims that XLNT has qualities "that only exist with respect to medical devices cleared by the FDA." *Id.* ¶¶ 33, 44. These statements include, among others:

- XLNTbrain is "Beyond Baseline Concussion Tests." *Id.* ¶ 32.
- XLNTbrain offers "The First Complete Online Concussion Test and Management Program for All Sports and Levels." *Id.*
- "[C]linical-caliber post-concussion evaluations to monitor severity and the recovery progress." *Id.* ¶ 33.

- "XLNTbrain Sport provides clinical-caliber concussion care giving subscribers a complete solution that's easy to use, affordable and adds a 'virtual neurologist' for the team." *Id.*
- "Implementing the XLNTbrain Concussion Management Program helps safely guide athletes back to gameplay after a concussion has been sustained." *Id.*
- "XLNTbrain offers a complete feature set when compared to other solutions." *Id.*
- "XLNTbrain offers a 'virtual neurologist' to athletic teams." *Id.*
- "Regarding post-injury testing, XLNTbrain provides 'baseline comparisons [that] provide clinical caliber post-concussion evaluations to monitor severity and the recovery progress." *Id.*
- "XLNTbrain provides a Daily Symptom Checklist for athletes to complete." *Id.*
- "[A] medical professional reviews data from XLNTbrain test and can lead to a 'sign off' on an athlete's return to gameplay." *Id.*
- XLNTbrain "helps answer the most common question, 'when can I play again?' Dr. Kerasidis created a tool that guides the decision-making process, giving all-involved individuals a recovery care plan that includes daily monitoring of symptoms, progressive physical and cognitive exertion exercises and a timeline to safely return to gameplay." *Id.* ¶ 35.

XLNTbrain makes these statements despite its absence from the FDA's list of approved devices for assessing head injury and despite not having filed a premarket regulatory submission with the FDA.[5] *Id.* ¶ 43.

D. Procedural History

ImPACT Applications filed its initial Complaint on October 25, 2019, alleging claims of false advertising in violation of the Lanham Act, 15 U.S.C. § 1525(a), and common law unfair competition against XLNTbrain, Harry Kerasidis, M.D., Steven E. Lewis, and John Does 1–10. ECF No. 1. XLNTbrain and Dr. Kerasidis answered on January 6, 2020, ECF No. 15, and filed a Motion for Judgment on the Pleadings, ECF No. 16, the following day.

[5] XLNTbrain admits in its Answer to Plaintiff's Amended Complaint, ECF No. 21, that it "has not yet been reviewed by the FDA for approval as a Class II medical device." ECF No. 21 ¶ 15.

On January 21, 2020, ImPACT Applications filed a Notice of Dismissal, voluntarily dismissing all claims against Steven E. Lewis and the John Doe defendants. ECF No. 17. The same day, ImPACT Applications, XLNTbrain, and Dr. Kerasidis filed a joint Stipulation of Voluntary Dismissal stipulating that Dr. Kerasidis would be dismissed, leaving XLNTbrain as the sole defendant. ECF No. 18.

Also on January 21, 2020, ImPACT Applications filed an Amended Complaint against XLNTbrain, ECF No. 19,[6] which XLNTbrain answered on February 4, 2020, ECF No. 21. XLNTbrain then filed the instant Motion for Judgment on the Pleadings on April 21, 2020. ECF No. 21. ImPACT Applications responded in opposition on May 8, 2020, ECF No. 25, and XLNTbrain replied on May 22, 2020, ECF No. 26. On May 27, 2020, ImPACT Applications requested leave to file a surreply, ECF No. 27, which XLNTbrain opposes, ECF No. 29.

II. MOTION FOR LEAVE TO FILE SURREPLY

The Court denies ImPACT Applications' Motion for Leave to File Surreply because XLNTbrain does not introduce any new information in its Reply that ImPACT Applications did not previously have an opportunity to address.

"Unless otherwise ordered by the Court, surreply memoranda are not permitted to be filed." Loc. R. 105.2(a) (D. Md. 2018). "Typically, '[s]urreplies may be permitted when the moving party would be unable to contest matters presented to the court for the first time in the opposing party's reply.'" *Tamarian Carpets, LLC v. Ahmadi & Sons, Inc.*, No. GLR-12-2571, 2013 WL 3771375, at *2 (D. Md. July 16, 2013) (brackets in original) (quoting *Khoury v. Meserve*, 268 F. Supp. 2d 600, 605 (D. Md. 2003)). ImPACT Applications' Motion for Leave to

[6] Plaintiff also filed a brief response to XLNTbrain's original Motion for Judgment on the Pleadings, asserting that the motion was mooted by the Amended Complaint. ECF No. 20. The Court agreed and denied XLNTbrain's first Motion for Judgment on the Pleadings as moot on July 2, 2020. ECF No. 28.

File Surreply, however, does not provide any explanation for why additional briefing is warranted here. ECF No. 27. Instead, ImPACT Applications states only that the "attached surreply is constrained to address arguments raised in the Reply that are either new or require a response[,]" but then fails to attach a surreply to its Motion. *Id.* at 1.[7] Moreover, a review of XLNTbrain's Reply reveals no new arguments. *See* ECF No. 26. Rather, the Reply only addresses arguments thoroughly discussed by ImPACT Applications in its Opposition. *See id.* Consequently, the Court denies ImPACT Applications' Motion for Leave to File Surreply.

III. MOTION FOR JUDGMENT ON THE PLEADINGS

A. Standard Of Review

Pursuant to Rule 12(c), "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). In ruling on a Rule 12(c) motion, courts apply "the same standard as motions brought under Rule 12(b)(6)." *Massey v. Ojaniit*, 759 F.3d 343, 347 (4th Cir. 2014) (citing *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999)). To survive a Rule 12(b)(6) motion, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Courts will dismiss complaints under Rule 12(c) if "after accepting all well-pleaded allegations in the plaintiff's complaint as true and drawing all reasonable factual inferences from those facts in the plaintiff's favor, it appears certain that the plaintiff cannot prove any set of facts in support of his claim entitling him to relief." *Edwards*, 178 F.3d at 244. This Court's role is to test "the sufficiency of the complaint," and not to "resolve the merits of the plaintiff's claims or any disputes of fact." *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 474 (4th Cir. 2014).

[7] Pin cites to documents filed on the Court's electronic filing system (CM/ECF) refer to the page numbers generated by that system.

As such, the Court will assume all well-pleaded factual allegations in the complaint to be true. *See Belmora LLC v. Bayer Consumer Care AG*, 819 F.3d 697, 702 (4th Cir. 2016).

B. Discussion

1. False Advertising Under The Lanham Act, 15 U.S.C. § 1125(a)

The Lanham Act prohibits "false or misleading description[s] of fact, or false or misleading representation[s] of fact" that "misrepresent[] the nature, characteristics, qualities, or geographic origin of [the speaker's] or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a). A plaintiff who brings a claim under the Lanham Act must allege:

> (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another's product; (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.

Scotts Co. v. United Indus. Corp., 315 F.3d 264, 272 (4th Cir. 2002). XLNTbrain's arguments in the instant case center on the first element of a Lanham Act claim: whether or not ImPACT Applications has adequately alleged a misrepresentation of fact that is actionable under the Lanham Act. *See* ECF No. 23 at 7–22.

In order to be actionable under the Lanham Act, "[a]n alleged misrepresentation of fact must be able to be reasonably interpreted as a statement of objective fact." *EndoSurg Med., Inc. v. EndoMaster Med., Inc.*, 71 F. Supp. 3d 525, 554 (D. Md. 2014). A statement of objective fact is a specific and measurable claim, "capable of being shown true or false in a way that admits of empirical verification." *Id.*; *Pizza Hut, Inc. v. Papa John's Int'l, Inc.*, 227 F.3d 489, 496 (5th Cir. 2000). "Statements of opinion are generally not actionable under the false advertising provision

of the Lanham Act." *EndoSurg Med., Inc.*, 71 F. Supp. 3d at 554. Puffery is one such form of non-actionable statements of opinion. "Puffery is an exaggerated statement which no reasonable buyer would be justified in relying on or a claim of superiority so vague that nothing can be understood from it except that it is an opinion." *Id.*

Additionally, in order for a statement to be actionable under the Lanham Act, a plaintiff must show that "the contested statement or representation [is] either false on its face or, although literally true, likely to mislead and to confuse consumers given the merchandising contexts." *Pediamed Pharm., Inc. v. Breckenridge Pharm., Inc.*, 419 F. Supp. 2d 715, 728 (D. Md. 2006). "A plaintiff need not provide evidence of consumer deception" where the advertisement is literally false. *Ferring Pharm., Inc. v. River's Edge Pharm., LLC*, No. AW-09-02601, 2010 WL 3087419, at *3 (D. Md. Aug. 6, 2010). However, where a plaintiff's claim relies on an implied falsehood, "a plaintiff must demonstrate, by extrinsic evidence, that the challenged [advertisements] tend to misled or confuse consumers." *Id.* (brackets in original) (quoting *Pediamed, Inc.*, 419 F. Supp. 2d at 728)

"In analyzing whether an advertisement . . . is literally false [*i.e.*, false on its face], a court must determine, first, the unambiguous claims made by the advertisement . . ., and second, whether those claims are false." *PBM Prods., LLC v. Mead Johnson & Co.*, 639 F.3d 111, 120 (4th Cir. 2011) (ellipses in original) (quoting *Scotts Co.*, 315 F.3d at 274). "A literally false message may be either explicit or conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated." *Id.* When "evaluating claims asserting literal falsity by necessary implication, courts have emphasized the limits of this theory of liability, holding that not 'all messages implied by an advertisement will support a finding of literal falsity." *Design Res., Inc. v. Leather*

Indus. of Am., 789 F.3d 495, 502 (4th Cir. 2015) (quoting *Clorox Co. P.R. v. Proctor & Gamble Commercial Co.*, 228 F.3d 24, 35 (1st Cir. 2000)). "The greater the degree to which a message relies upon the viewer or consumer to integrate its components and draw the apparent conclusion, . . . the less likely it is that a finding of literal falsity will be supported." *Id.* (ellipsis in original) (quoting *Clorox Co. P.R.*, 228 F.3d at 35). Moreover, "[c]ommercial claims that are implicit, attenuated, or merely suggestive usually cannot fairly be characterized as literally false." *Id.* (brackets in original) (quoting *Clorox Co. P.R.*, 228 F.3d at 35).

Finally, when the relevant product in a Lanham Act false advertising claim is regulated by the FDA—such as in the instant case—the Court must consider the interaction between the Lanham Act and the Food, Drug, and Cosmetics Act ("FDCA") when evaluating whether a plaintiff's Lanham Act claim is actionable. *See Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993). No private right of action exists under the FDCA, *see* 21 U.S.C. § 337(a), and a plaintiff may not use the Lanham Act "as a vehicle by which to enforce the [FDCA] and the regulations promulgated thereunder." *Mylan Labs., Inc.*, 7 F.3d at 1139. Rather, Lanham Act "claims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA[.]" *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, No. 96-2459-JWL, 1997 WL 94237, at *6 (D. Kan. Feb. 16, 1997). For example, "a plaintiff may not maintain a Lanham claim alleging only that the defendant has failed to disclose that the FDA has not approved its product." *Id.* Nor may a plaintiff bring a claim "that the very *act* of placing a drug on the market . . . somehow implies (falsely) that the drug had been 'properly approved by the FDA.'" *Mylan Labs., Inc.*, 7 F.3d at 1139 (emphasis in original). Such theories are, "quite simply, too great a stretch under the Lanham Act." *Id.* However, affirmative misrepresentations, including an explicit false statement

of FDA approval, are generally actionable, even if the product is regulated by the FDA. *Id.*; *Braintree Labs., Inc.*, 1997 WL 94237, at *6.

2. ImPACT Applications Has Not Alleged An Actionable False Advertising Claim Under the Lanham Act

ImPACT Applications alleges three categories of allegedly false statements: (1) false implications of FDA approval; (2) misleading suggestions that XLNTbrain products possess the qualities of FDA-approved devices; and (3) statements of superiority. The Court addresses each category of statement below and finds that ImPACT Applications' claims are exactly the type of claims that are non-actionable under the Lanham Act.

a. False Implications of FDA Approval[8]

First, ImPACT Applications alleges that XLNTbrain's statements regarding its devices, products, and/or services are false and misleading because they imply that XLNTbrain's products have been reviewed or approved by the FDA when they have not. *See e.g.*, ECF No. 19 ¶ 37 (alleging XLNTbrain's statements are misleading because the FDA has stated that "only cleared devices can make th[o]se claims"); *id.* ¶ 38 (alleging XLNTbrain's social media statements are statements of superiority that are misleading because they "suggest that

[8] ImPACT Applications argues that XLNTbrain has waived this argument under Fed. R. Civ. P. 12(g)(2) by not raising it in its original Motion for Judgment on the Pleadings, ECF No. 16—a motion the Court denied, without prejudice, as moot, ECF No. 28. ECF No. 25 at 20–21. Federal Rule of Civil Procedure 12(g)(2) provides that "[e]xcept as provided in Rule 12(h)(2) or (3), a party that makes a motion under this rule must not make another motion under this rule raising a defense or objection that was available to the party but omitted from its earlier motion." Fed. R. Civ. P. 12(g)(2). Federal Rule of Civil Procedure 12(h)(2), however, states that "[f]ailure to state a claim upon which relief can be granted . . . may be raised . . . by a motion under Rule 12(c)[.]" Fed. R. Civ. P. 12(h)(2). Thus, the plain language of Rule 12 does not appear to explicitly prohibit the arguments XLNTbrain includes in the instant Motion for Judgment on the Pleadings. *See Ennenga v. Starns*, 677 F.3d 766, 773 (7th Cir. 2012) (holding that Rule 12(g)(2) does not prohibit a new Rule 12(b)(6) argument from being raised in a successive motion). Moreover, courts routinely exercise discretion in applying Fed. R. Civ. P. 12(g)(2). *Aviles-Cervantes v. Outside Unlimited, Inc.*, 276 F. Supp. 3d 480, 487 (D. Md. 2017); *see also Dart Drug Corp. v. Corning Glass Works*, 480 F. Supp. 1091, 1095 n.3 (D. Md. 1979) ("[a] complaint is always vulnerable to a challenge for legal sufficiency[, and] it is far more efficient to treat the arguments prior to more extensive discovery.") Thus, as a matter of judicial efficiency, this Court will consider all of XLNTbrain's arguments in the pending Motion for Judgment on the Pleadings.

XLNTbrain possesses FDA medical device clearance or possesses the qualities of an FDA cleared medical device"); *id.* ¶ 49 (alleging that the statements outlined in the Complaint are "general misrepresentations regarding the effectiveness and safety of XLNTbrain devices, products, and/or programs that falsely or misleadingly imply FDA review and/or approval"); *id.* ¶ 52 (asserting that XLNTbrain's statements suggest that XLNTbrain's test is "a medical device cleared by the FDA that is marketed to consumers to help assess, diagnose, or manage head injury").

"False advertising claims based on allegations of implied governmental approval have not been allowed, for 'the law does not impute representations of government approval . . . in the absence of explicit claims.'" *Merck & Co., Inc. v. Mediplan Health Consulting, Inc.*, 425 F. Supp. 2d 402, 417 (S.D.N.Y. 2006) (ellipsis in original) (quoting *Avon Prods., Inc. v. S.C. Johnson & Son, Inc.*, 984 F. Supp. 768, 796 (S.D.N.Y. 1997)); *see also Ethex Corp. v. First Horizon Pharm. Corp.*, 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002) ("The decisions in this area have refused to allow plaintiffs to state a claim based on implicit representations of FDA approval"). ImPACT Applications does not point to any statement or representation by XLNTbrain that explicitly declares FDA review or approval. Thus, the Court finds ImPACT Applications has not alleged an actionable claim for false advertising under the Lanham Act based on this category of statements. Moreover, allowing a Lanham Act claim to proceed where a plaintiff does not point to any statement or representation in the defendants' advertising declaring FDA approval or review, but rather where the plaintiff tries to rely on a theory that the very act of placing a drug on the market "somehow implies (falsely) that the drug had been 'properly approved by the FDA[,]'" would, in effect, allow the plaintiff "to use the Lanham Act

as a vehicle by which to enforce the [FDCA.]" *Mylan Labs., Inc.*, 7 F.3d at 1139. Such a use of the Lanham Act is prohibited. *See id.*

b. Misleading Suggestions That XLNTbrain Products Possess The Qualities Of FDA-Approved Devices

ImPACT Applications next alleges that XLNTbrain's statements about its products, devices, and/or services are misleading because they suggest that XLNTbrain's products have qualities that only exist in medical devices cleared by the FDA. *See, e.g.*, ECF No. 19 ¶ 33 (presenting a bullet list of allegedly misleading claims concerning concussion screening, return-to-play assessments, diagnosis, and care, and alleging that these statements are misleading because they "suggest that the [XLNTbrain] test has qualities that only exist with respect to medical devices cleared by the FDA"); *id.* ¶ 36 (asserting that the statements outlined in paragraphs 33, 34, and 35 are factually misleading statements about XLNTbrain devices and services because they "suggest that XLNTbrain devices, products and/or services possess qualities only FDA-cleared medical devices have"); *id.* ¶ 39 (alleging that XLNTbrain's statement that it markets a "comprehensive, web-based, fully integrated sport concussion device" is misleading and "has a tendency to deceive the consuming public into believing that XLNTbrain offers benefits that are equivalent to an FDA-cleared medical device").

Nowhere in the Complaint, however, does ImPACT Applications specify what qualities XLNTbrain products allegedly cannot have because the products lack FDA approval. *See Engler v. Harris Corp.*, No. GLR-11-3597, 2012 WL 3745710, at *4 ("Because the central purpose of the complaint is to provide the defendant 'fair notice of what the plaintiff's claim is and the grounds upon which it rests,' the plaintiff's legal allegations must be supported by some factual basis sufficient to allow the defendant to prepare a fair response.") (quoting *Twombly*, 550 U.S. at 556 n.3). Can XLNTbrain not have a complete concussion management program? ECF No. 19

¶ 33. Is it impossible for XLNTbrain's post-concussion evaluations to be clinical-caliber? *Id.* Can only FDA-approved devices provide a Daily Symptom Checklist? *Id.* Nor is it clear to the Court that a device that has not been approved by the FDA—that has not even requested approval, *id.* ¶ 43—cannot have the qualities of an FDA-approved device. *See E. Shore Markets, Inc. v. J.D. Assocs. Ltd. P'ship*, 213 F.3d 175, 180 (4th Cir. 2000) ("[the Court] need not accept as true unwarranted inferences, unreasonable conclusions, or arguments"). This confusion is only increased by ImPACT Applications' admission that it does not allege "FDA approval is necessary to compete in the . . . space" in which ImPACT Applications and XLNTbrain both operate. ECF No. 25 at 13.

With respect to this category of allegedly false and misleading statements, the Amended Complaint as pleaded requires the Court to interpret and apply the FDCA in order to determine what qualities only an FDA-approved device can have and determine, before the FDA has had an opportunity to do so, whether XLNTbrain's products have those qualities. Thus, the Court finds that ImPACT Applications has again failed to allege misrepresentations that can support a false advertising claim under the Lanham Act. *Belcher Pharm., LLC v. Hospira, Inc.*, No. 8:17-cv-2353-T-30JSS, 2018 WL 4643292, at *3 (M.D. Fla. Apr. 9, 2018) ("'[A] Lanham Act claim [that] requires direct application or interpretation of the FDCA or FDA regulations' is within the FDA's jurisdiction.") (quoting *Healthpoint, Ltd. v. Stratus Pharm.*, 273 F. Supp. 2d 769, 786 (W.D. Tex. 2001)); *Braintree Labs., Inc.*, 1997 WL 94237, at *6 ("[C]laims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA[.]"); *see also Ethex Corp.*, 228 F. Supp. 2d at 1055 ("[T]his Court would be forced to determine FDA policy to determine the truth or falsity[,] . . .

this type of claim is better left to the FDA who has the experience in enforcing and interpreting its own complicated regulations[.]").

c. Statements Of Superiority

Finally, ImPACT Applications alleges that XLNTbrain's statements of superiority or implied superiority are false and misleading because they imply that XLNTbrain's tests are superior to ImPACT Applications' tests, which cannot be true because ImPACT Applications' tests have FDA approval while XLNTbrain's tests do not. ECF No. 19 ¶ 32 (alleging that XLNTbrain's statements that it is "Beyond Baseline Concussion Tests" and "The First Complete Online Concussion Test and Management Program for All Sports and Levels" are false and misleading statements of superiority because XLNT brain lacks clearance by the FDA as a medical device); *id.* ¶¶ 45–46 (alleging that XLNTbrain's claim of having a greater feature set than the ImPACT test is a misleading claim of superiority because of "the simple fact that only ImPACT is cleared by the FDA as a medical device"). The Court finds that ImPACT Applications has failed to sufficiently allege falsity with regard to these alleged statements of superiority.

Regarding the first two statements of superiority, nowhere in the Amended Complaint does ImPACT Applications allege that XLNTbrain does not have products other than—*i.e.*, "beyond"—baseline concussion testing, *see id.* ¶ 32; nor does the Court understand ImPACT Applications to allege that XLNTbrain's statement that it is "The First Complete Online Concussion Test and Management Program for All Sports and Levels" is literally false, *id.* ¶¶ 32–34, 36.[9] Instead, ImPACT Applications claims these statements are false and misleading

[9] The Court need not decide for the purposes of this memorandum opinion, but it is also likely these statements are non-actionable puffery. Puffery "a claim of superiority so vague that nothing can be understood from it except that it is an opinion." *EndoSurg Med., Inc.*, 71 F. Supp. 3d at 554.

only because they necessarily imply XLNTbrain is superior to ImPACT Applications, which cannot be true because ImPACT Applications has FDA approval and XLNTbrain does not. It is unclear, if not unlikely, however, that a device that is not approved by the FDA can never be superior in any respect to an FDA-approved device—*e.g.*, can never be more complete or have more features. *See E. Shore Markets, Inc.*, 213 F.3d at 180 ("[The Court] need not accept as true unwarranted inferences, unreasonable conclusions, or arguments[.]"); *United Black Firefighters of Norfolk v. Hirst*, 604 F.2d 844, 847 (4th Cir. 1979) (concluding that, at the motion to dismiss stage, a court need not accept all factual allegations devoid of any reference to actual events). Moreover, XLNTbrain has not been denied approval by the FDA—rather it never sought approval—so the FDA has not declared XLNTbrain inferior in some measurable way. ECF No. 19 ¶ 43; ECF No. 21 ¶ 43. Thus, ImPACT Applications' allegations regarding these two statements of superiority are insufficient to support a false advertising claim under the Lanham Act.

ImPACT Applications' allegations regarding XLNTbrain's claim of a comparatively more complete "feature set" are similarly insufficient to support a claim for false advertising under the Lanham Act. The Amended Complaint attaches the chart of features that XLNTbrain's "feature set" statement is based on, yet does not specifically claim that this chart contains false information regarding the offerings of each competitor. ECF No. 19-1. Rather, ImPACT Applications only contests a statement summarizing the chart: "XLNTbrain offers a complete feature set when compared to other solutions[.]" ECF No. 19-1; *see* ECF No. 19 ¶ 33. ImPACT Applications alleges this statement is misleading because, like with the other statements of superiority, XLNTbrain cannot be superior because it is not cleared by the FDA as a medical device while ImPACT Applications is FDA-approved. ECF No. 19 ¶¶ 45–46. However, as

discussed above, this conclusory claim is wholly unsupported, as it is unclear that lack of FDA approval has any relation to the completeness of a product's "feature set" or to a product's relative superiority.

ImPACT Applications has failed to allege in its Amended Complaint a false statement or misrepresentation sufficient to support a claim for false advertising under the Lanham Act. Thus, the Court grants XLNTbrain's request for judgment on the pleadings with regard to ImPACT Applications' Lanham Act claim and dismisses Count I of the Amended Complaint.

3. ImPACT Applications Has Not Alleged An Actionable Claim For Unfair Competition Under Maryland Common Law

Because the Parties seem to agree that ImPACT Applications' Lanham Act claim and state common law claim are evaluated under the same test, ECF No. 23 at 22; ECF No. 25 at 20; *see also Scotch Whisky Ass'n v. Majestic Distilling Co., Inc.*, 958 F.2d 594, 597 (4th Cir. 1992) (agreeing with the district court's decision to apply the same test to the Lanham Act false advertising claim and to the unfair competition actions under Maryland common law), the Court finds that ImPACT Applications also fails to state a claim of unfair competition under Maryland common law. Consequently, the Court grants XLNTbrain's request for judgment on the pleadings regarding ImPACT Applications' unfair competition claim and dismisses Count II of the Amended Complaint.

IV. CONCLUSION

For the foregoing reasons, ImPACT Applications' Motion for Leave to File Surreply is denied and XLNTbrain's Motion for Judgment on the Pleadings is granted. A separate Order shall issue.

Date: March 16, 2021

/s/
GEORGE J. HAZEL
United States District Judge